REMARKS

Status of the Claims

Claims 1-19 are pending and under consideration in this application. All the pending claims stand rejected. After entry of the amendments made herein, claims 1-7 and 10-23 will be pending and under consideration in this application, claims 20-23 having been added and claims 8 and 9 having been cancelled without prejudice to their being presented in a separate application and claims 20-23 having been added. New claims 20-23 and the amendment to claims 3, 12, 18, and 19, which are supported by the instant specification (e.g., at page 8, line 17, to page 14, line 11) and the drawings (e.g., Figs. 1-4), add no new matter. Grammatical amendments and typographic error corrections are also made to the claims and these also add no new matter.

35 U.S.C. §112, second paragraph, rejections

Claims 1-19 stand rejected as allegedly being indefinite for failing to particularly point and distinctly claim the subject matter that Applicants regard as the invention.

Claim 1 has been amended to essentially incorporate the limitation specified in claims 8 and 9 and claims 8 and 9 have been cancelled. Claims dependent on claim 9 have been amended to be dependent on claim 1. These amendments, which are supported by the instant specification (e.g., at page 8, line 17, to page 14, line 11) and the drawings (e.g., Figs. 1-4), add no new matter. Amended claim 1 clearly indicates how restenosis is predicted by the claimed method and that an unchanged concentration within 48 hours of an intervention predicts restenosis. Thus, the rejection on page 2, lines 14-17, is rendered moot by the amendment to claim 1.

In that claims 8 and 9 have been cancelled, the rejections of claims 8 and 9 on page 3, lines 1-8, are moot.

In light of the above considerations, Applicants respectfully request that the rejections under 35 U.S.C. §112, second paragraph, be withdrawn.

35 U.S.C. §103(a) rejections

Claims 1-19 stand rejected as allegedly being unpatentable over Eguchi et al. and Oda. Applicants respectfully traverse this rejection.

Applicants understand from the comments on page 4, line 1, to page 7, line 11, of the Office Action the Examiner's position to be that Eguchi et al. and Oda render the methods of the instant claims obvious. Applicants strongly disagree with this position.

First, neither reference discloses or even remotely suggests the application of the method it describes to the prediction of restenosis following an intervention. The method disclosed by Eguchi et al. merely measures the levels of L-PGDS before and after a procedure (PTCA) to treat angina as a correlate for the success of the procedure itself. There is no disclosure or suggestion of any complications of such a procedure, let alone restenosis. In particular, there is no mention or suggestion that measurements of L-PGDS concentration be made to predict any occlusive condition, let alone restenosis, that might occur as result of such a procedure. In addition, the occlusion disclosed by Eguchi et al. (angina) is due to thrombosis (i.e., arteriosclerotic plaques). In contrast, restenosis occurs due to the proliferation of smooth muscle cells within three to six months after PTCA. Thus, also because the mechanisms by which the two diseases arise are entirely different, Eguchi et al. provides no motivation to practice the method of instant invention.

In Example 4 of Oda, measurements of L-PGDS were made purely with the purpose of correlating the level of L-PGDS with the presence or absence of a cardiac condition (angina pectoris). There is no disclosure, or even the slightest suggestion, that these measurements be made as a predictor of any post-intervention occlusive condition, let alone restenosis.

Moreover, while in the present invention comparisons are made between the levels of L-PGDS in a subject at different time points, in both Eguchi et al. and Oda comparisons to test for the presence of non-intervention-related ischemic conditions are between patients with the conditions and normal subjects. In other words, in the present invention, contrary to the teachings of the cited references, the absolute concentration of L-PGDS is not the critical factor; rather it is the change (or lack thereof) in an individual that is important. Furthermore, in both references the changes seen in the levels of L-PGDS in the ischemic conditions described are increases, whereas in the present invention no change in the concentration of L-PGDS in a body

is an indication that the patient will develop restenosis and an increase in the level of L-PGDS is an indication that restenosis will not develop in the patient.

In light of the above considerations, Applicants respectfully request that the rejections under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

In summary, for the reasons set forth above, Applicants maintain that the pending claims patentably define the invention. Applicants request that the Examiner reconsider the rejections as set forth in the Office Action, and permit the pending claims to pass to allowance.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' undersigned representative can be reached at the telephone number listed above. Applicants submit herewith a request for an automatic extension of time and a check in payment of the extension of time. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 11283-014001.

Respectfully submitted,

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